



## Uniform Formulary Medical Necessity Criteria for Leukotriene Modifiers

**Drug Class** - Leukotriene modifiers. This drug class includes two leukotriene inhibitors, Accolate (zafirlukast) and Singulair (montelukast), and the 5-lipoxygenase inhibitor Zyflo (zileuton).

**Background** - After evaluating the relative clinical and cost effectiveness of the leukotriene modifiers, the DoD P&T Committee recommended that Zyflo be designated as non-formulary under the Uniform Formulary. This recommendation has been approved by the Director, TMA.

**Effective Date:** 16 Jan 2008

Patients currently using Zyflo may wish to consult their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Leukotriene Modifiers <sup>1,2</sup>

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs)	Mail Order	Retail Network
		cost share for up to a 90 day supply	cost share for up to a 90 day supply	cost share for up to a 30 day supply
Non-Formulary (Tier 3)	Zyflo	Not available <sup>2</sup>	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	Accolate Singulair	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic (Tier 1)	-	\$0	Generic cost share applies	Generic cost share applies
<ol style="list-style-type: none"> <li>1. Active duty cost share always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.</li> <li>2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.</li> </ol>				

## Medical Necessity Criteria for Zyflo

The non-formulary cost share for Zyflo may be reduced to the formulary cost share IF one or more of the following criteria are met:

1. Use of BOTH of the formulary leukotriene modifiers is contraindicated: Singulair (montelukast), Accolate (zafirlukast).
2. The patient has experienced significant adverse effects from BOTH of the formulary leukotriene modifiers: Singulair (montelukast), Accolate (zafirlukast).
3. Use of BOTH of the formulary leukotriene modifiers has resulted in therapeutic failure: Singulair (montelukast), Accolate (zafirlukast).
4. The patient previously responded to Zyflo and changing to a formulary leukotriene modifier would incur an unacceptable clinical risk (e.g., asthma patients stabilized on Zyflo).

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the August 2007 meeting & approved by the Director, TMA on 17 Oct 2007. For more information, please see the August 2007 [DoD P&T Committee minutes](#).

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TRICARE Management Activity,  
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Skyline 5, Suite 810, 5111 Leesburg Pike,  
Falls Church, VA 22041-3206

